Veterans Walk for Health Subject Checklist



ENROLLMENT ID: _1	<u>1.</u>
RANDOMIZATION ID: _1	2

VISIT 3	- Visit 6 Visit 3 Date: / / .	-
Flow Chart Reference	BRIEF DESCIPTION	Check as complete
3.1	Document height/ weight and BMI. (SC)	
	 Record in CPRS Cover Sheet (before RD opens VDF in CPRS). 	
	scale used (must be same scale used at visit 1)	
3.2	If participant is diagnosed with HTN (SC)	
	If SBP>160 and/or DBP>95 the participant must be put on hold until his physician	
	gives medical clearance to continue.	
	• (If participant put on hold, have them sign a new <i>Medical Clearance Form</i> . Give	
	participant phone card and complete <i>Payment Record/Receipt</i> . Contact the	
	participant's physician for medical clearance - if granted have physician sign the	
	Medical Clearance Form, then place it in the Participant's Study File. Reschedule Visit 3 once medical clearance has been received. If medical clearance is not	
	received, complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor,	
	document termination of study participation in CPRS.)	
3.5	Give participant phone card (SC)	
	 Complete Payment Record/Receipt and have the participant sign. 	
3.6	Schedule Visit 4 (SC)	
	 This appointment needs to be five to seven weeks after visit 1. 	
	Give patient an appointment card or write in on Calendar.	
	Note appointment in your planner.	
3.8	Make 2 copies of <i>Calendar</i> pages completed since Visit 2 if participant is	
	in group 1 or 2 (SC)	
	Original stays with participant.	
	copy to RD with participant name and last four digits of the SSN.	
	copy to Participant's Study File. SOC from Possiling Survey (SC)	
	SOC from Baseline Survey (SC)	
	 provide RD with pages 4-7 of the Baseline Survey labeled with participant name and last four digits of the SSN. 	
	Transition from SC to RD	
3.7.	Query for Exercise Related Symptoms and Adverse Events (RD)	
(3.13,	Ask participant if they have had any of the following new symptoms or worsening of	
3.15)	existing symptoms since Visit 2: Shortness of breath, Chest pain, Headache,	
,	Faintness, Dizziness, Any other problems.	
	(If yes, complete an Adverse Event Form and fax to Ann Arbor. Follow all	
	instructions on Adverse Event Form /Fax Cover Sheetthis may be delegated to SC.	
	If participant is put on hold, have them sign a new <i>Medical Clearance Form</i> . Have SC contact participant's physician to ask them for medical clearance - if granted have	
	physician sign the <i>Medical Clearance Form</i> , then put it in the study file. Have SC	
	reschedule Visit 3 medical clearance received. If medical clearance is not received,	
	have SC complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor,	
	document termination of study participation in CPRS.)	
3.11.	Review Activity Log (RD)	
	Group 1 Review Calendar, determine average minutes walked per day.	
	 Group 2 Review Calendar, determine average step count per day. 	
	Groups 3 Upload Sportbrain, determine average step count per day.	

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Flow Chart Reference	BRIEF DESCIPTION	Check as complete
3.12.	 Set new walking goals (RD) Record on Visit Documentation Form Consider 10-25% increase in step count or time increase of 5 or 10 minutes with participant. 	
3.14.	 Update SOC from Baseline Survey. (RD) Ask participant to update the copy of pages 4-7 of the Baseline Survey by marking only the answers that have changed since Visit 1. 	
3.16	 Nutritional Counseling (RD) Use updated SOC (give this updated SOC back to the SC). Use motivational interviewing techniques. 	
3.16.	Set new nutritional goals. (RD) • Document on Visit Documentation Form.	
3.16	Distribute nutritional/walking handouts as appropriate. (RD)	
3.18	 Visit Documentation Form to Ann Arbor (SC) If CPRS template, print note, obliterate participant name and SSN, write enrollment ID on the top margin. Send to Ann Arbor. 	
3.18	Obtain updated SOC from RD, file in participant folder.	
4.0	Reminder call to participant before next study visit (SC) • Date of reminder call:// • Remind participant to bring calendar (if in group 1 or 2). • Remind participant to wear pedometer to visit (if in group 2 or 3).	

VISIT 4	(Reinforcement)	Date:	1	1 .
4.1	 Document height/ weight and BMI. (SC) Record in CPRS Cover Sheet scale used (must be same scale used at visit 1) 			
4.2	 If participant is diagnosed with HTN (SC) If SBP>160 and/or DBP>95 the participant must gives medical clearance to continue. (If participant put on hold, have them sign a neparticipant phone card and complete Payment participant's physician for medical clearance - Medical Clearance Form, then place it in the Polisit 4 once medical clearance has been received received, complete a Participant Dropout/Term document termination of study participation in 	ew Medical Clear Record/Receipt. if granted have participant's Studed. If medical clean	rance Form. Contact the physician sigry File. Resch	Give en the nedule ot
4.5	 Give participant subject with phone card (SG Complete Payment Record/Receipt and have the 	· ·	gn.	
4.6	 Schedule Visit 5 (SC) This appointment needs to be 11 to 13 weeks a Give patient an appointment card or write in o Note appointment in your planner, note to send in planner. 	n <i>Calendar.</i>	s prior to app	ointment

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Flow Chart	BRIEF DESCIPTION	Check as
Reference		complete
4.7	Explain to participant that he is to wear an Actical for a full 7 days prior	
	to next study visit (SC)	
	Will be sent to him 9 days prior to next visit.	
	 Confirm that he still has Actical Use Handout, if not dispense a new one. 	
	Record dates that the device will be worn on the Actical Wearing Log. Dispense the	
	log to the participant and remind him how to complete it.	
	Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant's correct address is on <i>Crosswalk 2.</i> Add the participant address is on <i>Crosswalk </i>	
4.11	Make 2 copies of <i>Calendar</i> pages completed since Visit 3 if participant is	
	in group 1 or 2 (SC)	
	Original stays with participant.	
	Copy to RD with participant name and last four digits of the SSN.	
	Copy to Participant's Study File. COO from Participant's Comment (CO)	
	SOC from Baseline Survey (SC)	
	Give updated pages 4-7 of the Baseline Survey to the RD for today's visit. Transition from SC to RD.	
	Transition from SC to RD	T
4.8.	Query for Exercise Related Symptoms and Adverse Events (RD)	
(4.14,	Ask participant if they have had any of the following new symptoms or worsening of	
4.16)	existing symptoms since Visit 3: Shortness of breath, Chest pain, Headache,	
	 Faintness, Dizziness, Any other problems. (If yes, complete an Adverse Event Form and fax to Ann Arbor. Follow all 	
	instructions on <i>Adverse Event Form /Fax Cover Sheet</i> this may be delegated to SC.	
	If participant is put on hold, have them sign a new <i>Medical Clearance Form</i> . Have SC	
	contact participant's physician to ask them for medical clearance - if granted have	
	physician sign the <i>Medical Clearance Form</i> , then put it in the study file. Have SC	
	reschedule Visit 4 once medical clearance received. If medical clearance is not	
	received, have SC complete a <i>Participant Dropout/Termination Form</i> and fax it to	
4.10	Ann Arbor, document termination of study participation in CPRS.)	
4.12	Review Activity Log (RD)	
	Group 1Review Calendar, determine average minutes walked per day	
	Group 2	
	Review Calendar, determine average step count per day	
	Groups 3	
	 Upload Sportbrain, determine average step count per day 	
4.13	Set new walking goals (RD)	
	Record on Visit Documentation Form	
	 Consider 10-25% increase in step count or time increase of 5 or 10 minutes with 	
	participant.	
4.15	Update SOC from Baseline Survey. (RD)	
	 Ask participant to update the copy of pages 4-7 of the Baseline Survey again by 	
	marking only the answers that have changed since Visit 3.	
4.17	Nutritional Counseling (RD)	
	Use updated SOC (give updated SOC to SC).	
	Use motivational interviewing techniques.	
4.17	Set new nutritional goals. (RD)	
	Document on Visit Documentation Form.	
4.17	Distribute nutritional/walking handouts as appropriate (DD)	
4.17	Distribute nutritional/walking handouts as appropriate (RD)	

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4.19	Visit Documentation Form to Ann Arbor (SC)
	If CPRS template, print note, obliterate participant name and SSN, write enrollment
	ID on the top margin.
	Send to Ann Arbor in monthly shipment.
4.19	Obtain updated SOC from RD, file in participant folder
4.20	Send Actical to participant by overnight mail 10 days prior to Visit 5 (SC)
	 Set up Actical on Actireader, write user identity (Enrol. ID and V#), start date/time,
	ht/wt. Confirm battery life extends beyond date participant is to wear the Actical.
	 Log randomization ID and date dispensed on Actical Log.
	File overnight mail airbill with Actical Log.
4.21	Call Participant to confirm Actical was received (SC)
	Date of call:/
	Reminder to start wearing Actical the morning of/ to get 7 full
	days of data, and to bring Actical and Actical Wearing Log to appointment.
	 Remind participant to bring calendar (if in group 1 or 2).
	 Remind participant to wear pedometer to visit (if in group 2 or 3).

VISIT 5 (Reinforcement) Date: / / .

Flow Chart Reference	BRIEF DESCIPTION	Check as complete
5.1	 Document height/ weight and BMI. (SC) Record in CPRS Cover Sheet (before RD opens VDF in CPRS) scale used (must be same scale used at visit 1). 	
5.2	 If participant is diagnosed with HTN (SC) If SBP>160 and/or DBP>95 the participant must be put on hold until his physician gives medical clearance to continue. (If participant put on hold, have them sign a new Medical Clearance Form. Give participant phone card and complete Payment Record/Receipt. Contact the participant's physician for medical clearance - if granted have physician sign the Medical Clearance Form, then place it in the Participant's Study File. Reschedule Visit 5 once medical clearance has been received. If medical clearance is not received, complete a Participant Dropout/Termination Form and fax it to Ann Arbor, document termination of study participation in CPRS.) 	
5.4	 Obtain Actical and Actical Wearing Log from participant (SC) Upload Actical data to computer to make sure that it recorded properly (at least a full 7 days of data) Save file to be sent with monthly shipment to Ann Arbor. Maintain a copy of the Actical Wearing Log and send original to Ann Arbor. Record that Actical was returned on the Actical Log. (If Actical did not record at least 7 full days of data, re-dispense an Actical and record on the Actical Log. Give participant an Actical Wearing Log, phone card and complete a Payment Record. Reschedule Visit 5 at least 7 full days from today, up to 14 days from today. Give the participant an appointment card and document it in your planner.) 	
5.6	Give participant phone card (SC) • Complete Payment Record/Receipt and have the participant sign.	
5.7	 Schedule Visit 6 (SC) This appointment needs to be 23 to 25 weeks after visit 1. Give patient an appointment card or write in on <i>Calendar</i>. Note appointment in your planner, note to send Actical 10 days prior to appointment in planner. 	

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F 0	Explain to participant that ha is to wear an Actical for a full 7 days prior to	
5.8	Explain to participant that he is to wear an Actical for a full 7 days prior to	
	next study visit (SC)	
	Will be sent to him 9 days prior to next visit. Confirm that he still has Actical Use Handout, if not dispense a new one.	
	 Confirm that he still has Actical Use Handout, if not dispense a new one. Record dates that the device will be worn on the Actical Wearing Log. Dispense the log 	
	to the participant and remind him how to complete it.	
	 Confirm the participant's is at same address as on <i>Crosswalk 2</i>. 	
5.12	Make 2 copies of <i>Calendar</i> pages completed since Visit 4 if participant is in	
02	group 1 or 2 (SC)	
	Original stays with participant.	
	copy to RD with participant name and last four digits of the SSN.	
	copy to Participant's Study File.	
•	SOC from Baseline Survey (SC)	
	Give updated copy of pages 4-7 of the Baseline Survey for today's visit.	
	Transition from SC to RD	
5.9	Query for Exercise Related Symptoms and Adverse Events (RD)	
(5.14,	Ask participant if they have had any of the following new symptoms or worsening of	
5.16)	existing symptoms since Visit 4: Shortness of breath, Chest pain, Headache, Faintness,	
0.10)	Dizziness, Any other problems.	
	• (If yes, complete an <i>Adverse Event Form</i> and fax to Ann Arbor. Follow all instructions	
	on Adverse Event Form /Fax Cover Sheetthis may be delegated to SC. If participant	
	is put on hold, have them sign a new <i>Medical Clearance Form</i> . Have SC contact participant's physician to ask them for medical clearance - if granted have physician	
	sign the <i>Medical Clearance Form</i> , then put it in the study file. Have SC reschedule Visit	
	5 once medical clearance received. If medical clearance is not received, have SC	
	complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, document	
	termination of study participation in CPRS.)	
5.13	Review Activity Log (RD)	
	Group 1	
	Review <i>Calendar</i> , determine average minutes walked per day	
	Group 2	
	Review <i>Calendar</i> , determine average step count per day Croups 3	
	Groups 3	
5.15	Upload Sportbrain, determine average step count per day Set new walking goals (RD)	
5.15	Record on Visit Documentation Form	
	 Consider 10-25% increase in step count or time increase of 5 or 10 minutes with 	
	participant.	
5.17	Update SOC from Baseline Survey. (RD)	
3 1.7	Ask participant to update the copy of pages 4-7 of the <i>Baseline Survey</i> again by marking	
	only the answers that have changed since Visit 4.	
5.18	Nutritional Counseling (RD)	
	Use updated SOC (then return to SC).	
	Use motivational interviewing techniques.	
5.18	Set new nutritional goals. (RD)	
	Document on Visit Documentation Form.	
5.18	Distribute nutritional/walking handouts as appropriate (RD)	
5.20	Visit Documentation Form to Ann Arbor (SC)	
	If CPRS note, print, obliterate name and SSN, write enrollment ID on the top margin.	
	Send to Ann Arbor.	
5.20	Collect Updated SOC from RD, file in participant folder	
5.20	Send to Ann Arbor.	_

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	erence	DRIEF DESCIFITION	comple
	6 (Reinforcement)	Date: / / . BRIEF DESCIPTION	Check
VIOLE			
	Remind participant to wear pedo	ometer to visit (if in group 2 or 3).	
	Remind participant to bring cale		
		al the morning of/ to get 7 full land <i>Actical Wearing Log</i> to appointment.	
	Date of call://	ol the marning of / / to get 7 full	
5.22	Call Participant to confirm Actic	al was received (SC)	
	File overnight mail airbill with A	ctical Log.	
	 Log randomization ID and date d 	·	
		te user identity (Enrol. ID and V#), start date/time, extends beyond date participant is to wear Actical.	
5.21		rernight mail 10 days prior to Visit 6 (SC)	
	on a disk at the site.	-	
		g to Ann Arbor in monthly shipment. ownload to Ann Arbor, store one on your hard drive or	
		ing Log in participant's study file.	
5.20		File download to Ann Arbor (SC)	

		,	
Flow Cha		BRIEF DESCIPTION	Check as
Reference			complete
6.1	Docur	ment height/ weight and BMI. (SC)	
	•	Record in CPRS Cover Sheet (before RD opens VDF in CPRS).	
	•	scale used (must be same scale used at visit 1).	
6.2	If par	ticipant is diagnosed with HTN (SC)	
	•	If SBP>160 and/or DBP>95 the participant must be put on hold until his physician gives	
		medical clearance to continue.	
	•	(If participant put on hold, have them sign a new <i>Medical Clearance Form</i> . Administer	
		Final Survey, collect all devices and calendar pages. Give participant phone card and t-	
		shirt and complete <i>Payment Record/Receipt</i> . Contact the participant's physician for	
		medical clearance - if granted have physician sign the <i>Medical Clearance Form</i> , then	
		place it in the Participant's Study File. Reschedule final nutritional counseling once	
		medical clearance has been received. If medical clearance is not received, complete a	
		Participant Dropout/Termination Form and fax it to Ann Arbor, document termination of study participation in CPRS.)	
6.4	۸dmir	y i i	
0.4	Aumin	nister Final Survey (SC)	
	•	Add Randomization ID to top of <i>Final Survey</i> .	
	•	Remind participant that it will take ~20-30 min. to complete, that he does not have to complete anything that he doesn't feel comfortable completing, and that he can ask you	
		if he has questions. Ask if the participant would like to complete the survey	
		independently or if he would like you to read it to him.	
	•	Review any skipped answers with participant to make sure they were skipped	
		intentionally and not as an oversight.	
6.5	Obtai	n Actical and Actical Wearing Log from participant (SC)	
0.0	•	Upload Actical data to computer to make sure that it recorded properly (at least a full 7	
		days of data). Save file, send file and <i>Actical Wearing Log</i> to Ann Arbor.	
	•	Record that Actical was returned on the <i>Actical Log</i>	
	•	(If Actical did not record at least 7 full days of data, re-dispense an Actical and Actical	
		Wearing Log and record on the Actical Log. Give participant a phone card and complete	
		a <i>Payment Record</i> . Reschedule Visit 6 at least 7 full days from today, up to 14 days	
		from today. Give the participant an appointment card and document appointment in	
		your planner.)	

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6.5, 6.11	Obtain Digiwalker / safety strap or Sportbrain / cable / safety strap from	
·	participant if in group 2 or 3 (SC)	
	Record as returned on the <i>Digiwalker Log</i> or <i>Sportbrain Log</i> .	
	If in group 3, upload the Sportbrain so that data is available to the RD at today's visit.	
6.6	Give participant phone card and T-Shirt (SC)	
	Complete Final Payment Record/Receipt and have the participant sign	
6.11	Collect Calendar pages from participant if in group 1 or 2 (SC)	
	Make two copies of pages completed since visit 5.	
	 Add participant name and last four digits of the SSN to the top margin of one copy, give to RD for today's visit. 	
	 File other copy in Participant's Study File. 	
	SOC from Final Survey (SC)	
	Copy of pages 4-7 of the Final Survey, give to RD for today's visit	
	Transition from SC to RD	
6.7	Query for Exercise Related Symptoms and Adverse Events (RD)	
(6.12)	Ask participant if they have had any of the following new symptoms or worsening of	
()	existing symptoms since Visit 4: Shortness of breath, Chest pain, Headache, Faintness,	
	Dizziness, Any other problems.	
	• (If yes, complete an <i>Adverse Event Form</i> and fax to Ann Arbor. Follow all instructions on <i>Adverse Event Form /Fax Cover Sheet</i> this may be delegated to SC). If participant is	
	put on hold, have them sign a new <i>Medical Clearance Form</i> . Have SC contact	
	participant's physician to ask them for medical clearance - if granted have physician sign	
	the Medical Clearance Form, then put it in the study file. Have SC reschedule Visit 5	
	once medical clearance received. If medical clearance is not received, have SC	
	complete a <i>Participant Dropout/Termination Form</i> and fax it to Ann Arbor, document termination of study participation in CPRS.)	
6.13	Review Activity Log (RD)	
0.15	Group 1	
	Review <i>Calendar</i> , determine average minutes walked per day.	
	Group 2	
	Review <i>Calendar</i> , determine average step count per day.	
	 Groups 3 Review Sportbrain data (uploaded by SC), determine average step count/day. 	
6.15	Nutritional Counseling (RD)	
0.15	Use SOC from <i>Final Survey</i>	
	 Use motivational interviewing techniques. 	
6.15	Set new nutritional goals. (RD)	
	Document on Visit Documentation Form.	
6.15	Distribute nutritional/walking handouts as appropriate (RD)	
	Document Termination of Participation (SC)	
	Document termination of study participation in medical record.	
6.17	Visit Documentation Form to Ann Arbor (SC)	
	If CPRS note, print, obliterate name and SSN, write enrollment ID on the top margin.	
	Send to Ann Arbor.	
6.17	Actical Wearing Log and Actical File download to Ann Arbor (SC)	
	 Maintain a copy of Actical Wearing Log in participant's study file. 	
	Send original Actical Wearing Log to Ann Arbor in monthly shipment.	
	Send a copy of the Actical file download to Ann Arbor (email or disk) and maintain a copy	
	on your hard drive or on disk.	
6.17	Send original <i>Calendar</i> to Ann Arbor (SC)	

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